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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

MCNEIL, J

ART UNIT

PAPER NUMBER

1775

DATE MAILED:

4  
06/21/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/378,608

Applicant(s)

Ryan, Wayne L.

Examiner

Jennifer McNeil

Group Art Unit

1775



☒ Responsive to communication(s) filed on Nov 1, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-32 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☒ Claim(s) 1-27 is/are allowed.

☒ Claim(s) 28-32 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Specification*

1. The specification of the disclosure is objected to because reference is made to Patent 5,008,021 on page 2, line 11. This patent is related to silicates. Is it relevant? Page 1, lines 18-19 state, "requires the use of or more". Should it read, --requires the use of one or more--? Correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 28 and 30 require a control comprising a reticulocyte component and a component selected from a group including a reticulocyte component and other components. It is unclear why the reticulocyte component is included in the grouping as well as the overall control composition. The reticulocyte is required by the claim to be present in the control composition and its recitation as part of the optional grouping is confusing.

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***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 28, 29, 31, and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ryan et al (US 5,432,089). Ryan et al teach a reference control for use with manual and flow cytometric reticulocyte counting devices. The control contains RBCs loaded with RNA or DNA to simulate reticulocytes, and appropriate volumes of fresh RBCs in an isotonic solution (see column 4, lines 7-65, column 5, lines 11-20, column 7, lines 55-60). Visual displays from the instrument used are shown in Figures 2-4.

5. Claim 32 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ryan (US 5,270,208). Ryan teaches a white blood cell hematology control having red blood cells, white blood cells, and platelets in an isotonic solution for use in hematology instruments. The results are shown in histograms produced by instruments such as the Coulter STK-S, and the CEL-DYN 3000.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al (US 5,432,089) in view of Chupp et al (US 5,939,326). Ryan et al teach a reference control for use with manual and flow cytometric reticulocyte counting devices but does not specifically teach its use in conjunction with an instrument with bar code reading capabilities. Chupp et al teaches a hematology analysis instrument including reticulocyte capabilities and includes a bar code reader. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the control taught by Ryan et al in the instrument taught by Chupp et al for the purpose of calibration for reticulocyte content with the added ease of identification with the bar code reader.

*Allowable Subject Matter*

8. Claims 1-27 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or render obvious a hematology control composition comprising all of: a reticulocyte component, a white blood cell component, a red blood cell component, a nucleated red blood cell component, a platelet component, and a reticulated platelet component in an isotonic suspension medium.

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*Conclusion*


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patents to Francis et al, Zelmanovic et al, Wong et al, Ryan, Jacobs et al, Horton et al, Louderback et al, Runck et al, and Kim et al teach hematology controls and means for detection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer McNeil whose telephone number is (703) 305-0553. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached at (703) 308-3822.

When filing a fax in Group 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group are (703) 305-3599 for "Official" faxes and (703) 3055436 for "Unofficial" faxes.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

  
Jennifer McNeil  
Patent Examiner  
AU 1775

  
DEBORAH JONES  
SUPERVISORY PATENT EXAMINER